PRESCRIPTIONS for PROGRESS

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EDITORIAL

MMA 2003: Do We Know What We Need to Know?

MORRIS

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Since the passage of the Medicare Prescription Drug and Modernization Act of 2003 (MMA), providers, advocates, and the healthcare industry have been waiting to see the final regulations that will define the landscape of Medicare and state Medicaid plans going forward. These changes will impact the 35 million elderly on Medicare, but will also have special impact on the lives of those individuals (more than 6 million) younger than 65 who are eligible for both Medicare and state-federal Medicaid benefits because of disabilities. We have a special concern for a small but significant portion of this group—those individuals who are dually eligible because of their mental illnesses.

As with any change of this magnitude, the regulations themselves are extensive and complex. Considerable activity preceded their release, as various stakeholders tried to influence the Center for Medicare and Medicaid Services about the content of those regulations. That part of the process is over, and the tasks become understanding the new regulations and assisting those impacted by the changes to make the transition go smoothly. This issue of *Prescriptions for Progress* and the next will focus on information we need to move forward.

Whenever there is a major change in benefits that impacts vulnerable populations, there are predictable concerns—and usually a cluster of unexpected consequences. In the case of MMA, advocates and others are understandably concerned about impacts on care for mentally ill and disabled consumers—especially if consumers have to change from a successful medication regime to one that is less effective for them (but is covered by a new benefit plan). But there are additional policy concerns, including the impact on other benefits as states seek to reconfigure their Medicaid offerings. Other elements of the behavioral health industry are also scrambling to understand and prepare for the changed environment.

I have had the opportunity to speak with groups of consumers and behavioral healthcare providers in recent months about the pending changes. There was a striking similarity in the responses of the 2 groups: both groups know that there are changes coming; both groups want information; and both groups realize the time for accurate, clear information is very, very brief. The consumers with whom I spoke want choices—but they

A NOTE TO OUR READERS:

We designed *Prescriptions for Progress* for several audiences: state mental health and state Medicaid directors; psychiatrists in both the private sector and in public safety net programs; state pharmacy benefit managers; providers of services, whether public, private, or not-for-profit; and for consumers of mental health services, their families, and their allies in the advocacy community.

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We are anxious for your feedback on ways to improve this publication, and encourage you to contact us to comment on this issue or the first issue, to suggest future topics for us to address, and to alert us to other resources.

Send your comments to John Morris at jmorris@cnsmail.com

were emphatic about needing good information to inform those choices.

The lead article for this issue of *Prescriptions for Progress* is an analysis of MMA written by Carol Alter, MD, a psychiatrist who is director of the Treatment Effectiveness Now (TEN) Project, and Irvin L. "Sam" Muszynski, JD, Director of the Office of Healthcare Systems and Financing at the American Psychiatric Association. Carol and Sam have been working for the past year on this cause, and have devoted countless hours to understanding the implications of the new regulations. We delayed publication of this issue to ensure that we understood the implications as best we could, and could give our readers a reliable heads-up about what is coming. We think you will find their insights useful.

Elsewhere in this issue, well-known advocate Chris Koyanagi of the Bazelon Center for Mental Health Law provides a lucid distillation of some of the implementation challenges facing states, including a series of provocative questions about states' readiness to assist consumers in making these difficult transitions. We will devote most of the next issue of *Prescriptions for Progress* (Vol. 1, No. 3) to an extended interview with Ms Koyanagi and the results of a survey of states' readiness for these changes; she is currently conducting that survey on behalf of this newsletter.

You will also find a mini-glossary of terms and acronyms (box, at right) that have grown up around MMA, an illustrative chart of some of the major changes to the new world of prescription drug coverage as of January, 2006, a listing of major milestones in implementation of MMA, and some helpful charts prepared by the National Mental Health Association, reprinted here with their permission.

As is noted in several recent reports of the Henry J. Kaiser Family Foundation's Commission on Medicaid and the Uninsured (Jensen, 2005; Perry, Kitchman & Guyer, 2005) and re-emphasized by Carol Alter, Sam Muszynski, and Chris Koyanagi, these changes are immense—and the available time to prepare is extremely limited. We hope that this newsletter will encourage all stakeholders to move MMA preparation to the top of their priority list. We will need to be prepared to assist consumers in making the needed adjustments to ensure that their care continues uninterrupted and their recovery journey moves forward.

MINI-GLOSSARY

In this issue of *Prescriptions for Progress* we have occasionally used acronyms as a shorthand. These are in common use among those most familiar with the new Medicare coverage. As a convenience to those who don't spend full time on this subject, we provide this mini-glossary as a handy reference.

Clawback Provisions: The clawback will consist of a monthly calculation based on the combination of (a) the state's per capita spending on prescription drugs in 2003, (b) the state Medicaid matching rate, (c) the number of dual eligibles residing in the state, and (d) a "phase-down" percentage of state savings to be returned to the federal government, beginning with 90 % in 2006 and phasing down to 75 % in 2015." (Moore, J. and J. Ryan, NHPF Meeting Report: Implementing the New Medicare Drug Benefit: Challenges and Opportunities for States, National Health Policy Forum, August 31, 2004, p. 9.)

MA-PD, MA-PD SN: Medicare Advantage Prescription Drug Plans, also Medicare Advantage Special Needs Plans, are set up to serve a greater number of beneficiaries who have some special needs, such as serious and persistent mental illnesses.

MMA: The Medicare Prescription Drug and Modernization Act of 2003. This legislation creates a new Medicare pharmacy benefit for people who are dually eligible for Medicare and Medicaid.

PDP: Prescription Drug Plans are the companies that will manage the pharmacy benefit. Each service area defined by the Centers for Medicare and Medicaid Services must offer a choice of at least 2 prescription drug plans to consumers.

SSDI: Social Security Disability Income benefits are paid typically to individuals who have worked 5 out of the last 10 years. For individuals younger than 31 years, the requirements are a little different since they have not been in the work force as long.

SSI: Supplemental Security Income benefits are paid to individuals who receive lower income and are disabled, whether or not the individual has worked in the past. SSI children's disability benefits are paid to children who are younger than18 years, who are disabled, and whose parents or guardians receive lower income.

USP: The United States Pharmacopeia Convention, Inc. As described on their Web site, USP "helps to ensure that consumers receive quality medicines by establishing state-of-the-art standards that pharmaceutical manufacturers must meet. As the world's most highly recognized and technologically advanced pharmacopeia, USP provides standards for more than 3,800 medicines, dietary supplements, and other healthcare products." (www.usp.org, accessed 2/3/05).

QUESTIONS & ANSWERS

Frequently Asked Questions About MMA

QUESTION: What is it?

ANSWER: A major change to Medicare coverage that provides a pharmacy benefit to individuals who are both Medicaid- and Medicare-eligible. Often called by the shorthand "MMA," the full title of the bill is "Medicare Prescription Drug, Improvement and Modernization Act of 2003."

QUESTION: How can I learn more?

ANSWER: Well, reading this newsletter will help, we hope. Dr Alter and Mr Muszynski have been researching these regulation changes for some time. The Centers for Medicare and Medicaid Services (www.cms.hhs.gov) has lots of information on this topic, including the specifics of the new regulations—all 1,100 pages of them—that are discussed in this issue. The Treatment Effectiveness Now project has a Web site coming soon (www.tenproject.org), the Kaiser Family Foundation has an excellent Web site (www.kff.org) and the National Mental Health Association Web site (www.nmha.org) also has information. There is a handy chart of other resources at the bottom of page 7.

QUESTION: Isn't this something just for the elderly?

ANSWER: No, this also covers disability populations under the age of 65 who did not have a Medicare pharmacy benefit before, including individuals who are eligible for Medicare (via Supplemental Security Income or Social Security Disability Income) as well as Medicaid.

QUESTION: What is dual eligibility?

ANSWER: There is a general lack of awareness about the large group of people (approximately 6 million) who are eligible for health benefits from both state Medicaid programs and—because of a disability such as severe and persistent mental illness—from Medicare coverage, regardless of their age.

QUESTION: What's the impact on people with serious mental illnesses?

ANSWER: No one knows yet what the outcome will be, but it is known that effective in late Fall 2005, all individuals who are dually eligible will be automatically enrolled in a prescription drug plan. If they do not recognize their current medications in the new plan, they will have to opt out of the plan to which they have been auto-enrolled. This is a new experience for most people with serious mental illnesses.

QUESTION: Is this a voluntary change in coverage?

ANSWER: No, the new coverage is mandatory. At the present, there is no alternative, nor is there a plan to phase in coverage over time to allow for systems to adjust to the changes before all enrollees make the switch.

QUESTION: How ready are states for the changes?

ANSWER: No one is certain, but the next issue of *Prescriptions for Progress* will be devoted in large measure to that very question. The National Association of State Mental Health Program Directors did some analysis a few months back, before the regulations were published, and there was a range of state awareness/readiness.

QUESTION: Isn't this a financial windfall for states if they can shift their prescription drug costs from Medicaid (for which states have to pay a match) to Medicare?

ANSWER: No. There is a provision referred to as "clawback" that requires states to pay back to the federal government a portion of the monies that would be so diverted.

DID YOU KNOW?

"When I go to see my psychiatrist and he puts me on a certain medication...are they going to know every single plan, every single medication covered?"
New Jersey focus group participant with mental illness.

Source: Medicare's New Prescription Drug Benefit: The Voices of People Dually Covered by Medicare and Medicaid. Michael Perry, Michelle Kitchman, Jocelyn Guyer, January, 2005, p. 10.

THE MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003 (MMA)

MMA: Implications for Persons With Mental Illnesses

DID YOU KNOW?

The fear of not being able to secure a specific medication is greatest for those who use a carefully calibrated mixture of medications, or who have conditions for which emerging medications are currently being developed.

Source: Medicare's New Prescription Drug Benefit: The Voices of People Dually Covered by Medicare and Medicaid. Michael Perry, Michelle Kitchman, Jocelyn Guyer, January, 2005, p. 19.

Editor: We have invited Dr Alter and Mr Muszynski to provide details of the Medicare prescription drug benefit as described by the final rule that was released on January 21, 2005, with a special focus on the dual eligible population. Dr Alter is a psychiatrist and the Executive Director of Treatment Effectiveness Now (The TEN Project), which is a policy action organization affiliated with the Georgetown University Department of Psychiatry. The TEN Project is focused on access to care for patients with complex physical and mental health conditions. TEN has been working closely with others in the mental health advocacy community to educate policy makers about the clinical and economic evidence supporting appropriate care for patients who will receive the new Medicare drug benefit in January, 2006. Mr Muszynski is an attorney and Director of the Office of Healthcare Systems and Financing at the American Psychiatric Association. He has been working closely with other advocacy groups to formulate policy recommendations to the Center for Medicare and Medicaid Services (CMS) about the new program.

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Background of the MMA

The Medicare Prescription Drug and Modernization Act of 2003 (MMA) arose out of a need to provide an outpatient prescription drug plan for Medicare beneficiaries. While the majority qualify for Medicare based on their age, Medicare also provides coverage to approximately 6.5 million nonelderly patients who also receive Medicaid services (referred to as "dual eligibles"). There are several ways that Medicaid patients younger than 65 years of age may qualify for Medicare and thus be considered dual eligible. For example, if Medicaid patients younger than 65 have received disability payments (SSDI) for more than 2 years they can qualify for Medicare and receive benefits from both programs; a small but critical minority of these dual eligibles have mental illnesses. Currently, when a patient is dually eligible for Medicare and Medicaid, Medicare is the primary payer and Medicaid provides "wrap around" coverage. Since there was no Medicare outpatient drug benefit prior to the MMA, these dually eligible patients' medications were paid for by their Medicaid benefit. With the addition of the new Medicare drug benefit, the responsibility for that prescription drug benefit will shift to Medicare.

The MMA establishes a competitive market model approach for the new federal prescription drug benefit by having private entities (known as Prescription Drug Plans, or PDPs) manage it. Central to this arrangement is that each PDP will separately contract with and negotiate prices for medications with pharmaceutical manufacturers; CMS has established 34 PDP regions across the country and expects that the majority of the new drug benefit will be provided through plans that will be "at risk" plans. In other words, based on a risk adjustment model, plans will receive a set, or capitated, payment for each patient enrolled in their plan. In order to remain profitable, each plan will be challenged to keep costs low while at

the same time provide the requires services. CMS will allow these plans to implement formulary controls such as prior authorization, step therapy, and others in order to keep costs down. There are several key questions that surround the implementation of MMA from the policy, patient, and practitioner perspective. Many of these questions are similar. When considering that some of these dually-eligible individuals have thought disorders and may have difficulty evaluating all their options, some implementation questions have major implications. In the balance of this article, we identify some of these key questions and attempt to answer them. Keep in mind that this is a dynamic process and therefore all questions cannot be answered today. We all need to stay as informed as possible so that we can manage the process, not be managed by it.

First, from a policy/clinician perspective some key questions include: How are patients to be enrolled in the benefit? How will continuity of care be ensured during the transition to the new benefit? What formulary will a plan utilize? And what strategies will be used to manage the selected formulary? From the standpoint of the patient there are 3 fundamental questions:

1. How do I enroll?
2. What is included in the drug benefit package? and
3. What happens as I transition from my current Medicaid coverage to the new Medicare plan?

Interestingly, clinicians will be playing a critical role in the transition, as their patients and care plans may be directly impacted by the changes. Therefore, clinicians need to understand the changes that are taking place, be aware of the PDPs and formularies in their area, and be thinking ahead about how to minimize problems for their patients.

Elsewhere in this issue there are explanations and specific details about how coverage will change, but, in a nutshell, Medicaid reimbursement for psychiatric medications ceases on January 1, 2006, replaced by beneficiary participation in one of the PDPs funded by Medicare. In every area of the country, beneficiaries are required to have access to at least 2 plan options. The regulations published on January 21, 2005, and various CMS sub-regulatory guidelines, provide instructions for how these PDPs are to manage the pharmacy benefit.

Enrollment

Under the final regulations, dual eligibles will be automatically enrolled in a PDP in their area beginning as early as September, 2005. The PDP must be a "low-premium" plan, meaning that it must offer a benefit for a standard premium and cannot require additional payment from the beneficiary. If more than one low-premium plan exists in a geographic area, each dually eligible patient in that area will be randomly auto-enrolled in one of the plans. Patients will have an opportunity to switch from the plan they have been assigned to prior to January 1, 2006, or at any time thereafter; but they will have to do so by actively initiating the change. This automatic enrollment prior to the change-over date is a response to concerns that there would be an interruption in access to needed prescription medication during the period of enrollment.

While there are likely several advantages to assuring that patients will have coverage on January 1, 2006, it is not clear that the automatic enrollment process will match patients with the optimal coverage for them as individuals. The details of the formulary and management strategies for the pharmacy benefit by the PDPs are not factored into the auto-enrollment, and, as a result, there is the potential for a mismatch. Keep in mind that the PDPs may have financial risk, and so will be looking to control costs. Those patients who would like to choose an alternative plan will be able to access information about the formulary for that plan. PDPs are required to identify which drugs will be preferred and which will require prior authorization or be subject to fail-first or other step-therapy protocols. (For extensive treatment of private sector pharmacy management strategies such as "step therapy," see the interview with Bridget Eber in the first issue of *Prescriptions for Progress*, Vol. 1, No. 1.)

Who will actually facilitate this selection process for a class of patients who are cognitively impaired remains an unanswered question. Therefore, it is unclear how an informed selection of a plan (ie, in the best interests of the patient) can be made prior to the cessation of Medicaid coverage on December 31, 2005.

The primary issues for consumer and clinician advocates will be how to obtain accurate plan information and how to determine the

DID YOU KNOW?

A small, but critical, minority of dual eligibles has serious mental health issues and is at considerable risk of hospitalization if they miss their medications.

Source: Medicare's New Prescription Drug Benefit: The Voices of People Dually Covered by Medicare and Medicaid. Michael Perry, Michelle Kitchman, Jocelyn Guyer, January, 2005, p. 3.

DID YOU KNOW?

States will be required to finance a large share of the cost of providing Medicare Part D benefits to dual eligibles through payments to the federal government. According to one report, states can expect to pay an estimated $88.5 billion in mandatory "claw-back" payments to the federal government to redirect funds they would have spent providing prescription drugs to beneficiaries in Medicaid.

Source: State readiness for implementation of Medicare Part D for dual eligibles: a summary of plans and activities in 30 states. National Association of State Mental Health Program Directors, Health Systems Research Associates in collaboration with Advocates for Human Potential, December 1, 2004.

implications of this information for individual patient care. The compressed timeline and the broad scope of plan information to be assimilated present serious challenges for accurate analysis and timely action. All concerned (eg, state mental health authorities, community providers, individual practitioners, and consumer advocates) need to be thinking ahead about how to effectively communicate accurate information to people with mental illness and their representatives and how to assist them in making informed choices.

A major concern is that a beneficiary (or a beneficiary's representative) may look at the benefit plan to which he/she has been assigned and see that all of the psychiatric medications on which he/she has depended are on an approved formulary without fully understanding the restrictions that apply to accessing these medications. The instinctive response would be, "Okay, the drugs that have been working for me are covered, so I'm comfortable with this plan." That confidence may not be justified in all instances.

Transition to the new benefit

In addition to the final rule, several instructions from CMS have been and are currently being developed that address special issues of concern (ie, continuity of care for patients). The rule as it now stands requires that each plan have a "transition process for new enrollees' prescribed Part D drugs that are not on its formulary." The preamble states that CMS will offer additional guidance to PDPs on this process. It also specifies that the transition policy a plan devises should focus on particularly vulnerable populations, such as people with mental illnesses who are dually eligible. However, it is not clear at this writing that the transition guidance will provide protections that ensure that patients who are clinically stabilized will, in fact, have access to the same medications that have provided the stability.

Details and management strategies

The law is very specific about the fact that every PDP must include in its benefit package at least 2 medications from every category and class of medications. It also calls upon PDPs to use a framework of drug categories and classes devised by the United States Pharmacopeia (USP) as the basis for their formularies. That said, the regulations permit PDPs to use a broad range of utilization management procedures such as generic substitution, step therapy (fail first), and tiered copayments.

The law also states that PDPs cannot use their formularies to discriminate against any class of beneficiaries. CMS has used this as the authority to issue guidelines and will review each formulary and its utilization management protocols to ensure that it does not discriminate against a particular class of patients. A formulary that limits access to only 2 antidepressants or antipsychotics would not allow adequate range of prescribing options for many individuals with complex and persistent psychiatric disorders and should, in our view, be barred under the CMS guidelines. The CMS guidance on the process of formulary development clearly states that it will review not only a plan's adherence to the USP model but the specific formulary, to determine whether it includes drugs used by patients with special conditions such as mental illness or HIV disease. The sub-regulatory guidance specifically states that plans should include a majority of drugs for treatment of mental illness and HIV. Approval of narrow formularies by CMS would have enormous implications for physicians prescribing, and would likely add significant administrative burden to practices serving these 2 populations. Unfortunately, we have no actual experience to date on how CMS will actually rule on specific formularies and benefit management features.

One critical question arising out of the absence of a unified formulary recommendation from CMS is how the process a PDP will use to determine its formulary will actually work. CMS has stated that plans must employ a pharmacy and therapeutics (P&T) committee that includes, among others, experts in the care of the elderly and/or those with disabilities and at least 1 member who has no financial conflicts of interest. The regulations also stipulate a number of factors P&T committees must consider in arriving at their formulary conclusions, such as all available scientific evidence. P&T committees must document how they made their decisions about their final formulary.

Excluded drugs

The law has excluded from coverage a group of drugs that is important to the dual eligible population, benzodiazepines. However, the

final rule *does* give states the right to provide benzodiazepines and other noncovered drugs that are on the exclusion list, and to receive the federal Medicaid match for these drugs.

Exceptions requests and appeals process

The rule provides a process for beneficiaries to seek an exception to a financial or clinical tiering feature of a PDP formulary or to gain access to a drug not on the formulary.

Each of the PDPs must establish a coverage determination process for beneficiary exceptions requests. The process includes provisions for an expedited response (based on certain criteria) within 24 hours, or a standard timeframe, ie, no later than 72 hours after the decision.

Adverse coverage determinations can be redressed through an elaborate appeals process. This is a multi-staged process that extends beyond the PDP, and includes an Independent Review Entity, then an Administrative Law Judge, and finally the Medicare Appeals Council. It is instructive to note that criteria to determine the medical necessity of an exceptions request are unilaterally determined by the PDP. It does not appear that the process contemplates *de novo* review of the criteria.

Conclusion

The law and its implementation by CMS have profound implications for Medicare beneficiaries with mental illness. Whether the model established by the law will perform in a manner that is responsive to the clinical and prescribing needs of patients and physicians, or results in less favorable coverage, remains to be seen. The enrollment and implementation will occur over a very short period of time with significant clinical and economic consequences if patients are not properly informed about the changes. Central to any successful transition will be the involvement of providers: physicians, case managers, community mental health centers, and other mental health professionals who are currently responsible for care for these patients. As a community, it will be critical for us to have the information and resources to ensure that every patient who will be receiving the new benefit will understand the implications and make an appropriate choice of plan. In any case, the complexities of the law and the challenges of transition will require an unprecedented sophistication of response by the advocacy community.

FOR ADDITIONAL INFORMATION ON MMA AND DUAL ELIGIBLES

A number of organizations with concerns about people with disabilities have produced materials on MMA, and their Web sites are valuable resources for current information. In addition, of course, there is the Web site of the Center for Medicare and Medicaid Services.

Here is a listing of some useful links:

www.kff.org The Henry J. Kaiser Family Foundation. The Foundation has been a leader in reporting and analysis on the issue of MMA.

www.bazelon.org The Judge David L. Bazelon Foundation for Mental Health Law covers a wide range of policy and legal issues in mental health. Chris Koyanagi, Policy Director at the Bazelon Center, is the author of a piece in this issue and will report on a major national survey commissioned by Comprehensive NeuroScience for this newsletter.

www.nmha.org The National Mental Health Association (NMHA), the nation's oldest advocacy organization for people with mental illnesses, has a robust policy presence and posts regular updates and position statements on issues such as MMA.

www.cms.gov The Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for management of MMA. Details of the law, regulations, and sub-regulations can be found here.

www.nami.org The National Alliance for the Mentally Ill (NAMI), another prominent advocacy organization representing the interests of people with mental illnesses and their families. NAMI also regularly posts policy and issue statements on issues such as MMA.

www.psych.org The American Psychiatric Association (APA) frequently updates its Web site with information of interest to psychiatrists and others—such as MMA. Irvin Muszynski, one of the authors of an article in this issue, is Policy Director for the APA.

www.nasmhpd.org The National Association of State Mental Health Program Directors (NASMHPD) is the organization that represents the state mental health authorities in all of the states and territories. This Web site also contains a link to the NASMHPD Research Institute (NRI), a site that has state profiles and other useful information.

KEY ISSUES FOR DUAL ELIGIBLES

ISSUE: DUAL ELIGIBLES AND CONTINUITY OF CARE

PROPOSED REGULATIONS

- Enrollment will begin on November 15, 2005.
- Dual eligibles will be automatically enrolled in a PDP or MA-PD, if they do not enroll themselves, by the end of the initial enrollment period, which is May 15, 2006 (after their Medicaid coverage ends January 1, 2006).
- Dual eligibles required to enroll in lowest-cost plans (low-income subsidy will only cover premiums for these plans).

FINAL REGULATIONS

- CMS will begin the process of automatically enrolling dual eligibles as soon as plans have been chosen to participate in Part D (probably September 2005).
- Dual eligibles will have 6 weeks (starting November 15) to make any changes to their Medicare drug plan by January 1, 2006 to avoid gaps in coverage.
- After January 1, 2006, dual eligibles will be able to change plans whenever they want.
- Low-income subsidy will only cover premium for lowest-cost plan in area.

ISSUE: POLICIES REGARDING ACCESS TO MEDICATIONS & FORMULARY GUIDELINES

PROPOSED REGULATIONS

- Preamble encourages use of prior authorization, fail first, and step therapy.
- Plans must disclose to enrollees how formulary works, how to obtain copy of formulary, and cost-sharing provisions.
- Plans required to give 30 days' notice to beneficiaries of formulary changes.
- In preamble, CMS encourages plans to include representatives of various specialties on pharmacy and therapeutics (P&T) committees.
- CMS does not encourage off-label use of medications
- The proposed USP model guidelines for establishing drug formularies require Part D drug plans to include at least 2 drugs from each class.
- Older medications may be grouped with more costly, newer drugs in the same class. A plan then could include 2 older drugs, but no newer drugs in each class.

FINAL REGULATIONS

- No "grandfathering" requirement to ensure a consumer will receive medications they are currently stabilized on.
- "Transition process" will be established for consumers whose medications are not on their new plan's formulary.
- Plans must give 60 days' notice to beneficiaries of formulary changes.
- No provisions for public input/consumer comment into plans' P&T committee processes.
- No requirement for P&T committee representation for every specialty.
- No guarantees that plans would have to cover off-label uses of medications.
- Minimum requirement of at least 2 medications in each approved category and class (unless there are only 2 drugs in a class; in which case only 1 drug must be covered).
- Plans will not be required to provide unrestricted access to the 2 medications in each class, meaning that prior authorization, fail first, etc, could apply.
- CMS formulary guidance says agency will look for plans to cover a majority of medications in the antidepressant, antipsychotic, anticonvulsant classes.

SOURCE: National Mental Health Association Legislative Alert: "Government Issues Final Rules for Medicare Prescription Drug Benefit," February 16, 2005.

KEY ISSUES FOR DUAL ELIGIBLES

ISSUE: INVOLUNTARY DISENROLLMENT

PROPOSED REGULATIONS

- Proposed rules allowed plans to involuntarily disenroll individuals for disruptive behavior.
- Provides for expedited disenrollment process for disruptive behavior.
- Disruptive behavior is defined as "disruptive, unruly, abusive, uncooperative, or threatening."

FINAL REGULATIONS

- CMS has the right to refuse to allow fallback plans to involuntarily disenroll enrollees for disruptive behavior.
- No expedited disenrollment provision.
- To be disenrolled, an enrollee's behavior must "substantially" impair the plan's ability to provide services. Behavior is not considered disruptive if it is related to use of medical services or compliance (or non-compliance) with medical advice.
- "Reasonable accommodations" required for individuals with disabilities to be determined by CMS on a case-by-case basis or in exceptional circumstances that CMS deems necessary.

ISSUE: APPEALS PROCESSES FOR COVERAGE DENIALS AND REQUESTS FOR EXCEPTIONS FROM FORMULARY RESTRICTIONS AND COST-SHARING TIERS

PROPOSED REGULATIONS

- Standard determinations and exceptions (first level of appeal) made in 14 days.
- Expedited determinations and exceptions made in 72 hours.
- Redeterminations (second level of appeal) made 30 days from when date request is received.
- Deadline for reconsideration by an Independent Review Entity to be determined in contract with CMS.

FINAL REGULATIONS

- First level of appeal made in 72 hours.
- Expedited first level of appeals made in 24 hours.
- Redeterminations made 7 days from when request received.
- Expedited redeterminations made in 72 hours.
- Deadline for reconsideration by an Independent Review Entity is 7 days.
- Deadline for expedited reconsideration by an Independent Review Entity is 72 hours.
- No requirement for plans to cover medication at issue during appeals process.
- Coverage obtained through the exceptions process may extend no longer than 1 year (at the discretion of the plan). If not, enrollee may need to go through exceptions process on yearly basis.

COMMENTARY

Medicare Part D: Issues for State Agencies

DID YOU KNOW?

STATE WRAP AROUND COVERAGE

A number of states have introduced legislation during this session (as well as last session) that relates to the Medicare Part D prescription drug benefit. The majority of this legislation provides state-funded drug coverage that "wraps around" the Medicare benefit and includes non-Medicare Part D prescription drugs and/or provides assistance with Medicare Part D-related costs. Most of this legislation either creates or changes existing State Prescription Assistance Programs (SPAPs).

Source: National Mental Health Association (NMHA).

According to the NMHA, the states include: California (AB 75), Connecticut (HB 6687), Hawaii (HB 693 and SB 802), Maryland (HB 0324), Missouri (HB 0169, SB 0039, SB 0075) , New Hampshire (SB 163), New York (A. 1922 and S. 992), Rhode Island (H 7630 enacted in 2004), Tennessee (HB 2290 and SB 2309), and Virginia (HB 2714).

KOYANAGI

Chris Koyanagi, Policy Director, Bazelon Center. Former Vice President of Government Affairs, National Association of Mental Health

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established a voluntary, outpatient prescription drug benefit in Medicare (creating a new Part D of Medicare) to begin on January 1, 2006. The law provides substantial financial subsidies for poor and near-poor beneficiaries, as well as for elderly persons. The Part D benefit is available to persons with disabilities who qualify for Medicare through Social Security Disability Insurance (SSDI) and those who are dually eligible for Medicare and Medicaid because they also receive Supplemental Security Income (SSI) disability benefits.

Federal and state governments that will administer the new program will need to make extraordinary efforts to assure that all those who can benefit from Part D take advantage of it. This may require significant creativity and advance planning by state officials. Transition to this new plan could be problematic for many, and the dual eligibles who are younger than age 65 are at particular risk. They could lose coverage for some—or all—drugs if their transfer into Part D does not go smoothly.

Need for planning

State Medicaid agencies are now heavily involved in planning for Part D implementation as it affects their Medicaid populations. With the release of final Part D regulations by the Center for Medicare and Medicaid Services (CMS) in late January, many issues are a little clearer than before and Medicaid agencies are stepping up the pace of their planning. Specific issues for dual-eligible beneficiaries with serious mental illness may not, however, be getting appropriate attention in all states. Historically, certain state Medicaid agencies have close ties and working relationships with the state mental health authority. In others, the 2 agencies work warily together, have a poor relationship, or act independently. Successful implementation of Part D requires perhaps unprecedented levels of cooperation and joint action by Medicaid and mental health agencies in the states. Multiple issues must be addressed, crossing the boundaries between these agencies and potentially involving other state agencies and entities outside of government as well. This article raises questions about some important issues facing states and discusses some of the challenges for which states must plan.

Preparation time is brief

The timetable on Part D implementation, which is extremely tight, will put great pressure on state systems to respond. On December 31, 2005, all dual-eligible individuals (some 6.5 million people) lose most of their Medicaid prescription drug coverage. This group includes people with serious mental illness on SSDI whose benefit is so low that they also qualify for SSI. By January, 2006, these individuals must be signed up for a Part D drug plan, as they will no longer have Medicaid coverage.

The question is, how well prepared are states to deal with these issues? For example, dual-eligible Medicare beneficiaries are known to be significantly poorer, sicker, and to have less education and higher utilization of prescription drugs than other people on Medicare. Individuals with serious mental

illness in this group must also often grapple with cognitive impairments. They will clearly need assistance in understanding the changes caused by the MMA. While full Medicaid dual eligibles will be deemed eligible and automatically enrolled, obviating the need for them to apply for benefits, they have the option to opt-out of a plan and pick an alternative that better suits their needs. In order to avoid lapses in coverage of medications they currently use and need, they will need to act quickly. The slow rate of sign up for the Medicare drug cards by low-income individuals eligible for full subsidies under that program shows how confusion and suspicion can prevent people from acting in their own best interest on these issues.

Are states now planning outreach strategies specifically to this group of individuals with serious mental illness? Are they preparing information for them, and making plans to ensure that people do not opt out of a drug plan they do not like (but then fail to sign-up for an alternative)?

The impact on consumers

As they struggle to understand their options, individuals with serious mental illness will need to compare drug plan formularies. Do states plan to offer consumers analyses of the various plan formularies? Will front-line providers, particularly case managers, be trained on these plans and the law and stand ready to help individual consumers make appropriate decisions?

Individuals with serious mental illness, as a group, have significantly high rates of other, physical health ailments. The choice of an appropriate plan may be quite complicated for them, as they must not only seek coverage for the psychiatric medications they have been taking, but also other medications. How well are states anticipating these problems?

Some consumers with serious mental illness on Medicare are not eligible for Medicaid. However, they still may be eligible for the low-income subsidies under Part D. Moreover, if they fail to enroll in Part D by May 15, 2006, they incur penalties that may make

Chris Koyanagi of the Bazelon Center discusses MMA with Dr Kit Simpson of the Medical University of South Carolina.

DID YOU KNOW?

The provision of a special enrollment category for dual eligibles is particularly important as they are the only Medicare recipients who, if they don't enroll on their own, will be automatically assigned to an average or low-cost Part D plan on a random basis.

Source: Jensen, Richard, The New Medicare Prescription Law: Issues for Enrolling Dual Eligibles Into Drug Plans. Kaiser Commission on Medicaid and the Uninsured, January, 2005, p. 6.

future enrollment prohibitively expensive. (For example, people with incomes between 135% to 150% of poverty pay a premium penalty for life, which may be as high as 1% of the average premium amount per month.) Are state mental health authorities considering the needs of those consumers who are not dual eligible? To what extent will Medicaid or other state agencies be addressing the needs of these individuals (such as those on a state pharmacy assistance program)?

Part D allows drug plans to change coverage. Consumers with mental illnesses will be very vulnerable in such circumstances. To what extent are any state agencies looking ahead, past the initial implementation stage, and planning for on-going consumer assistance?

In addition, federal law does not include benzodiazapines in the Part D benefit. Will state Medicaid plans continue coverage for these important drugs for dual-eligible individuals after implementation of Part D? Will state mental health authorities cover them?

Except for individuals in the lowest income bracket, Part D requires some cost-sharing. Those with the lowest incomes and assets (income below 135% of poverty) receive a full subsidy for the out-of-pocket costs. Those with incomes between 135% and 150% of poverty and with assets less than $10,000/individual qualify for a reduced subsidy. They pay a $50 deductible, 15% coinsurance, and up to $5,100 in total spending, plus additional small copayments. Individuals with higher incomes and assets pay a deductible, coinsurance, copayments, and the full cost of drugs in the "donut hole" (which starts after they spend $2,250 on *covered* drugs but ends after they spend $3,600). As a result of these complicated cost-sharing arrangements, some consumers in the public system may find themselves obligated to pay out more for their medications than they can easily afford. What are states doing to protect very–low-income individuals who are in Part D?

Support for consumers

Consumers will need considerable assistance in dealing with Part D issues. Multiple outreach efforts, distribution of information materials, hands-on assistance in signing up for a plan, etc, all suggest that front-line staff must play a significant role. Are state mental health authorities planning how to work with providers around the state to, first of all, train those providers in Part D issues, and secondly to encourage and support their working with individuals or groups of consumers?

There is a significant minority of people eligible for Part D coverage who have major mental illness but who are not regularly seen within public mental health system clinics and programs. Homeless shelters, jails, houses for runaway youth, and various other non-mental health service settings may be appropriate places to reach such individuals. Have any state mental health authorities considered the complexities of reaching these individuals, or of the need to work with other state agencies to be sure that individuals with serious mental illness are reached?

This list of questions is not exhaustive. There are many complex policy and programmatic issues surrounding the implementation of Part D. It will be hard for any state to address all of these issues comprehensively and prevent all vulnerable populations from falling through the cracks. While those who are not dual eligible may not immediately take up Part D coverage—even though it would greatly benefit them—only the dual-eligible population (and in some states possibly the low-income prescription drug plan enrollees) stands to lose coverage in 2006 if they fail to successfully enroll in an appropriate plan. This population should, therefore, probably have priority in state agency planning.

A role for advocacy

In the mental health field, a number of quite effective advocacy groups exist. These groups may be helpful conduits for information to families of persons with serious mental illness and to the individuals themselves. Families could play a very important role in helping their loved ones make the appropriate decisions in a timely fashion. Advocates for other low-income populations could also play a role, if provided appropriate information and technical assistance on how to ensure individuals with severe mental illness receive the counseling they need to make a decision. For example, homeless workers and advocates could play a significant role in outreach.

PHARMACY BENEFITS FOR DUAL ELIGIBLES: NOW AND IN 2006

NOW

- Medications paid for by Medicaid.
- All FDA approved medications can be paid for, although states can impose utilization restrictions.
- State savings through management of pharmacy benefit can be reinvested.
- Appeal process at the state level.
- Complicated pharmaceutical regimens covered in most states, at least through over-rides.
- States manages pharmacy benefit.

JANUARY 2006

- Medications paid for by Medicare—through a pharmacy plan.
- Pharmacy plans may limit specific drugs covered by limiting number of medications covered in any class of medication (SSRIs, atypical antipsychotics, etc.)
- States expected to reimburse the federal government some share of cost savings from Medicaid through the so-called "clawback" provisions.
- National appeals process—looks cumbersome.
- No "grandfather" clause allowing for continuation of medications in new plans.
- Consumers will be auto-enrolled in low- or average-cost plans.

SUMMARY CHART OF MEDICARE DRUG BENEFITS

	GENERAL POLICY	BETWEEN 135% AND 150% FPL[1]	UNDER 135% FPL[2]	DUAL ELIGIBLE
ANNUAL PREMIUM	$35 per month ($420 annually)	Sliding scale	None	None
DEDUCTIBLE (PERSON PAYS IN FULL)	$250	$50	None	None
COPAYMENT	25% for drug costs between $250 and $2,250 100% for drug costs between $2,250 and $5,100	15% for drug costs between $50 and $5,100	$2-$5 copays for drug costs up to $5,100	Under 100% FPL: $1-$3 copays for drug costs up to $5,100 Above 100% FPL: $2-$5 copays for drug costs up to $5,100 No copays for drug costs over $5,100
"DONUT HOLE"	$2,850 gap in coverage	n/a	n/a	n/a
CATASTROPHIC COVERAGE FOR DRUG COSTS OVER $5,100	5% or copays $2-$5	Copays of $2-$5	100% covered	100% covered

[1] And assets below $10,000 for individuals and below $20,000 for couples
[2] And assets below $6,000 for individuals and below $9,000 for couples

SOURCE: National Mental Health Association Legislative Alert: "Government Issues Final Rules for Medicare Prescription Drug Benefit," February 16, 2005.

STANDARD & POOR'S

Report on State Healthcare Finances

DID YOU KNOW?

According to the National Mental Health Association, 2 states have established hotlines to help consumers with access problems—California (AB 74) and Missouri (HB 0169, SB 0039, SB 0075)—and North Dakota (HB 1465) provides a 60-90 day transition period during which the state can pay for medications for dual eligibles who are not covered.

Source: National Mental Health Association.

THE BUDGETARY OUTLOOK FOR STATE HEALTHCARE FINANCES IS TROUBLING. ACCORDING TO A REPORT ISSUED IN April 2004 by Standard & Poor's Credit Market Services division, economic recovery at the state level is proceeding, but remains uneven and below average in many areas of the country. In fact, since Standard & Poor's last issued its report card on state finances in September 2003, there have been credit downgrades for Indiana, Michigan, New Hampshire, Oregon, and Washington.

The level of downgrades is now close to that of the early 1990s, when 11 states were downgraded. Since 2001, Standard & Poor's has downgraded 10 states, with California experiencing 3 downgrades during this period. Seven states now have negative outlooks: Alabama, Arizona, Illinois, Kansas, Maine, New York, and Tennessee. According to the report, pressures on spending remain intense despite aggressive and consistent cost reduction measures implemented by the states over the past 3 years, and Standard & Poor's expects that the states will continue to explore methods to reduce expenditures.

WHAT THE "LETTER" RATINGS MEAN

What is a Standard & Poor's rating?

A credit rating is Standard & Poor's opinion on the general creditworthiness of an obligor, or the creditworthiness of issuers of capital market obligations. Over the years credit ratings have achieved wide investor acceptance as convenient tools for differentiating credit quality.

S&P's ratings are based on information provided by the issuer together with other information we consider reliable. Ratings may be changed, suspended, or withdrawn because of changes in or unavailability of information.

A rating does not constitute a recommendation to buy, sell, or hold a particular security. It does not comment on the suitability of an investment for a particular investor. S&P does not perform an audit in connection with any rating.

AAA: Extremely strong capacity to meet financial commitments. Highest rating.

AA: Very strong capacity to meet financial commitments.

A: Strong capacity to meet financial commitments, but somewhat susceptible to adverse economic conditions and changes in circumstances.

BBB: Adequate capacity to meet financial commitments, but more subject to adverse economic conditions

BBB- (minus): this is the lowest rating before non-investment grade.

BB: Less vulnerable in the near-term but faces major ongoing uncertainties to adverse business, financial and economic conditions.

B: More vulnerable to adverse business, financial and economic conditions but currently has the capacity to meet financial commitments.

CCC: Currently vulnerable and dependent on favorable business, financial and economic conditions to meet financial commitments.

CC: Currently highly vulnerable.

C: A bankruptcy petition has been filed or similar action taken but payments or financial commitments are continued.

D: Payment default on financial commitments.

UPDATES

If you'd like to receive regular email updates on Standard & Poor's Healthcare Credit Ratings, send an email to sarah_demann@mcgraw-hill.com. Please put *S&P Ratings* in the subject line.

NOT-FOR-PROFIT HEALTHCARE RATINGS ACTIONS, JANUARY 2005

Hospitals and Health Systems	State	Rating	Outlook	Action
Ascension Health*	MO	AA	Stable	New subordinate debt issue rated 'AA-'; 'AA' senior debt rating affirmed
Blessing Hospital	IL	A-	Stable	Rating affirmed
Cheshire Medical Center	NH	A+	Stable	Rating affirmed
Children's Healthcare of Atlanta	GA	AA	Stable	New issue
Community Medical Center	MT	BBB-	Negative	Rating affirmed and outlook revised to negative from stable
Daughters of Charity Health System	CA	BBB+	Stable	New issue
Delano Regional Medical Center	CA	BBB-	Stable	Rating affirmed
Duke University Health System*	NC	AA	Stable	Rating affirmed
Evanston Northwestern Healthcare Corp.	IL	AA+	Stable	Rating affirmed
Evergreen Center Inc.	MA	BBB-	Stable	New issue
Franciscan Services Corp. Obligated Group	OH	A-	Stable	Rating affirmed
Geisinger Health System	PA	AA-	Stable	Rating affirmed
Good Shepherd Medical Center	TX	BBB	Negative	Rating affirmed and outlook revised to negative from stable
Health Alliance of Greater Cincinnati	OH	A+ (ICR)	Stable	Rating affirmed
HealthEast	MN	BB+	Stable	Rating raised to 'BB+' from 'BB' and outlook is stable
Kuakini Health System	HI	BBB	Stable	Rating affirmed
Lancaster General Hospital	PA	A	Stable	Rating raised to 'A' from 'A-' and outlook is stable
Legacy Health System	OR	AA	Stable	Rating affirmed and outlook revised to stable from negative
Massachusetts Eye and Ear Infirmary	MA	BB+ (SPUR)	Stable	Rating affirmed
Memorial Healthcare	MI	BBB+	Stable	Rating raised to 'BBB+' from 'BBB' and outlook is stable
Memorial Hermann Healthcare System*	TX	A	Stable	Rating affirmed
Methodist Hospital of Houston	TX	AA/A-1+	Stable	Two separate new issues; rating affirmed
Montrose Memorial Hospital	CO	BBB-	Stable	Rating affirmed
Moses Taylor Hospital	PA	B-	Negative	Rating lowered to 'B-' from 'B' and outlook is negative
National Jewish Medical and Research Center	CO	BBB	Stable	New issue; rating affirmed
New Liberty Hospital District	MO	A (SPUR)	Positive	Rating affirmed and outlook revised to positive from stable
Oregon Health & Science University	OR	BBB+ (SPUR)	Stable	Rating affirmed
Phoebe Putney Memorial Hospital	GA	AA- (SPUR)	Stable	Rating affirmed
Scotland Memorial Hospital	NC	BBB+ (SPUR)	Stable	Rating affirmed
Scott and White Memorial Hospital and Scott, Sherwood and Brindley Foundation	TX	AA- (SPUR)	Stable	Rating affirmed
Scottsdale Healthcare	AZ	BBB+	Stable	Rating affirmed
Sharon Regional Health System	PA	A- (SPUR)	Stable	Rating affirmed and outlook revised to stable from negative
Southern Illinois Healthcare Enterprises	IL	A+ (SPUR)	Stable	New issue
SwedishAmerican Hospital	IL	A-	Stable	New issue; rating affirmed
Texoma Medical Center	TX	BBB-	Stable	Rating affirmed
University of Pennsylvania Health Services	PA	A	Stable	New issue; rating affirmed
Washoe Medical Center	NV	A-	Stable	New issue; rating affirmed
West Virginia University Hospital Inc.	WV	A+ (SPUR)	Stable	New issue

Long-Term Care and Human Service Providers	State	Rating	Outlook	Action
Carleton Willard Village	MA	A- (SPUR)	Stable	Rating affirmed
Learning Center for Deaf Children	MA	BB	Stable	Rating affirmed

*Disclosure Plus clients.

IN FUTURE ISSUES...

Number 3:
We will focus on the readiness of states, providers, and advocates to assist people with mental illnesses who are dually eligible prepare for the impending changes brought by MMA. Chris Koyanagi of the Bazelon Center on Mental Health Law will report on a survey she is conducting of state mental health and consumer affairs directors.

Number 4:
We will highlight research on managing pharmacy benefits and innovations in benefit design and management. Of special interest are interventions that increase adherence and impact on the use of high-cost services, such as emergency rooms and hospital days.

KEY DATES AND MILESTONES OF MMA FOR DUAL ELIGIBLES[1]

JUNE 6, 2005

- Deadline for companies to submit bids as Prescription Drug Plans (PDPs) or Medicare Advantage-Prescription Drug Plans (MA-PDs) to the Center for Medicare and Medicaid Services (CMS).

JULY 1, 2005

- Deadline for CMS to establish requirements and procedures for coordination between Part D plans and state pharmacy assistance programs and other insurers, including state Medicaid programs.

SEPTEMBER 2005

- CMS awards bids to PDPs and MA-PDs.

OCTOBER 1, 2005

- Deadline for transfer of responsibility for Medicare appeals from Social Security Administration to the Department of Health and Human Services.

NOVEMBER 15, 2005

- Enrollment period begins.

DECEMBER 31, 2005

- Medicaid drug coverage ends for "full benefit" dual eligibles.

JANUARY 1, 2006

- Part D Coverage begins for all beneficiaries enrolled in a plan.
- States begin to make monthly "clawback" payments to federal government for dual eligibles.
- Auto-enrollment of dual eligibles begins.

OCTOBER 15, 2006

- Deadline for Secretary of Health and Human Services to notify states of their annual per capita drug payment amounts for 2007 ("clawback" for dual eligibles).

[1] Adapted from Medicare Prescription Drug, Improvement, and Modernization Act Implementation Timeline: June 2004-December 2006 Key Dates, The Henry J. Kaiser Family Foundation, accessed via the Internet on March 9, 2005, at http://www.kff.org/medicare/medicare_timeline.cfm

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